

### REMARKS

Claims 1-4, 6, 7, 10, 11, and 14-24 are pending in this application.

Reconsideration and withdrawal of the rejections set forth in the Official Action are respectfully requested in view of this amendment and the following reasons. By this amendment, Claims 1-4, 6, and 7 have been amended, Claims 5, 8, 9, 12, and 13 have been canceled, and new Claims 19-24 have been added. The cancellation of Claims 5, 8, 9, 12, and 13 is made without prejudice or disclaimer to the subject matter contained therein.

Claim 1 has been amended to incorporate the features of Claim 5, which has been canceled without prejudice or disclaimer. In addition, the language of "at least two holes for passing fixing elements to be tightened to said bone and at least one assembly element integral with said body for attaching said bone-fixing member, said rigid body having" has been removed from the claim and has been added to new Claims 19 and 20. Other minor changes have been made for more clarification.

Claims 2-4 and 7 have been amended to depend upon new Claim 19 or Claim 20, and Claim 6 has been amended to depend upon Claim 1.

New independent Claim 21 recites similar features as Claim 1, with the exception of the description on the contacting surface. Support for the contacting surface recited in Claim 21 may be found at least on page 10, lines 18-24 of the present application as originally filed.

New Claims 22-24 depend directly or indirectly from Claim 21 and recite the features of original Claims 1 and 5. Hence, Claims 22-24 are supported by the present application as originally filed.

It is respectfully submitted that the above amendments introduce no new matter within the meaning of 35 U.S.C. §132. For at least these reasons, entry of the present Amendment is therefore respectfully requested. Accordingly, Applicant requests reconsideration and timely withdrawal of the pending rejections for the reasons discussed below.

### ***Rejections Under 35 U.S.C. §102***

Claims 1-3 and 5-8 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by U.S. Patent No. 6,235,033 issued to Brace, *et al.* ("Brace").

"Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)).

Claim 1, as amended, recites, *inter alia*:

said saddle clamp having a rigid body with **a contact surface** for contacting the vertebra and comprising **a saddle surface** configured to straddle the top of the pedicle between the transverse process and the superior facet when said saddle clamp is mounted on the vertebra, and **a second surface** configured to contact simultaneously said superior facet (emphasis added)

These recited features of Claim 1 were originally recited in Claim 5, which has been canceled without prejudice or disclaimer. The Examiner asserts that Brace teaches a device having a saddle shaped surface and a second surface (see, for example, Fig. 2).

As a preliminary matter, Applicant respectfully traverses the rejection because the cited prior art does not disclose each and every feature recited in original Claim 5, which has been incorporated into Claim 1. The Examiner merely presents a conclusory statement of anticipation without elaborating how Brace teaches all of the recited features of Claim 5. More specifically, in the Official Action, page 2, under the heading "Regarding Claims 5 and 7," the Examiner indicates that "Brace et al. teach a device having a saddle shaped surface and second passing holes." However, the Examiner fails to particularly point out:

which element(s) of the device 10 disclosed in Brace teaches the vertebra "having at one side thereof a pedicle, a superior facet with an edge, and a transverse process;"

which element(s) of the device 10 disclosed in Brace teaches a saddle surface "configured to straddle the top of the pedicle between the transverse process and the superior facet when said saddle clamp is mounted;" or

which element(s) of the device 10 disclosed in Brace teaches a second surface "configured to contact simultaneously said superior facet," as recited in Claim 1, and similarly recited in original Claim 5.

The Official Action is silent about these Claim features. Thus, the Official Action fails to establish a *prima facie* case of anticipation. Accordingly, it is respectfully requested that this final rejection be withdrawn.

Furthermore, Applicant notes that Brace *per se* does not disclose at least the above Claim features. In order for the structure shown in the Brace drawings to teach the above-cited features of Claim 1, the surface of the device 10 must have two surfaces; one of the two surfaces, corresponding to the saddle surface, must be configured to straddle the “top of the pedicle” between the “transverse process” and the “superior facet” when the superior is mounted; and the other one of the two surfaces, corresponding to the second surface, must be configured to contact simultaneously the “superior facet.” Apparently, in any description or illustration of Brace, these features are not found.

The presently claimed subject matter makes specific reference to the shape of the contact surface of the rigid body: the contact surface comprises a saddle surface and a second surface, the saddle surface being configured to straddle the top of the pedicle between the transverse process and the superior facet when said saddle clamp is mounted, and the second surface configured to contact said superior facet at the same time.

Applicant further submits that, to the extent that Brace can be said to comprise a saddle shaped surface, it is not disclosed nor obvious that the surface is shaped so that it would “straddle the top of the pedicle between the transverse process and the superior facet when said saddle clamp is mounted,” as recited in Claim 1. Furthermore, assuming

*arguendo* the surface of Brace could be considered as teaching the saddle surface of Claim 1, it still does not comprise any equivalent of the second surface "configured to contact simultaneously [i.e., when the saddle surface straddles the portions of the vertebra as above] said superior facet."

Claim 1, as amended, recites a *specific geometry* of the contact surface, which is not disclosed nor suggested by Brace. Thus, Applicant respectfully submits that Claim 1 is not anticipated by Brace at least because it fails to teach the above-cited features of Claim 1.

Furthermore, it is respectfully noted that the term "saddle surface" is to be understood in light of the specification.

1. The Examiner takes the position that although Claims are interpreted in light of the specification, limitations from the specification are not read into the claims, citing *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

2. The Examiner takes the position that in order for the term "saddle surface" to be defined with the meaning intended by the Applicant, the specification must set out the meaning "with reasonable clarity, deliberateness, and precision."

In connection with the first reason, Applicant submits that the *Van Geuns* decision cited by the Examiner is applicable when the specification presents a limitation which is absent in the claims. However, the term at issue "saddle surface" is already recited in Claim 1. Accordingly, the Examiner's first position, citing *In re Van Geuns*, is not sustainable for at least this reason.

Instead, Applicant believes that *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571-72, 7 USPQ2d 1057, 1064-1065 (Fed. Cir.), cert. denied, 488 U.S. 892 (1988), as cited in MPEP 2145 (VI), would be a more suitable standard to be applied. In accordance with this decision, limitations in a specification *may be read into terms in a Claim* if the specification provides evidence that this *should be* done.

As stated above, the specification, particularly, on page 10, lines 19-21, describes the saddle surface as being “defined generally between a down-turned arch 60 and an upturned arch 62 lying in transverse planes and having a common point 64 (saddle point).” In addition, the descriptions in the specification portion relate this to the shape of the pedicle, which is described as having roughly the same shape. Thus, a “generally arcuate surface,” which the Examiner alleges is a valid definition of a saddle surface, is not a proper interpretation of Claim 1.

In connection to the second reason, Applicant respectfully draws the Examiner’s attention to MPEP §2111.01 (IV), which is applicable when an applicant wishes to use “a definition of [a] term that is different from its ordinary and customary meaning(s).” The term “saddle surface” is a well-known mathematical term which designates a smooth surface having curves up on one direction, curves down in another, transverse direction, with a “saddle point” at which upward- and downward-curving arcs meet. Therefore, since the meaning Applicant wishes to impart to the term “saddle surface” is in line with this ordinary and customary meaning, Applicant respectfully disagrees with the other possible

interpretation offered by the Examiner, namely “nothing more than a generally arcuate surface, additional limitations directed to another arc or to hyperbolic paraboloids should not be read into the claims in the interpretation thereof,” as indicated on page 7, lines 15-17 of the Official Action.

Applicant respectfully submits that the meaning of a saddle surface is set out clearly, deliberately, and precisely. The specification, on page 10, lines 19-21, particularly states that “[t]he saddle surface 56 is defined generally between a down-turned arch 60 and an upturned arch 62 lying in transverse planes and having a common point 64 (saddle point).”

As can be understood from the term “defined,” this is not a mere exemplification of the surface, but rather is based on a reasonable understanding of the term.

Furthermore, regardless of whether the description of “saddle surface” as per page 10, lines 19-21 meets its ordinary and customary meaning, the meaning of “saddle surface” as per page 10, lines 19-21 should be primarily considered by the Examiner when interpreting the claims.

New independent Claim 21 explicitly describes the saddle surface according to page 10, lines 19-21. Thus, the Examiner’s interpretation of the term “saddle surface” apparently does not apply.

Claims 2-4, 6, 7, 10, 11, 14-20, and 22-24 depend directly or indirectly from Claim 1 or Claim 21, and thus are allowable for at least this reason.

Accordingly, Applicant submits that Brace does not teach each and every recited element of present Claims 1-4, 6, 7, 10, 11, and 14-18 as required for anticipation under 35

U.S.C. §102. Thus, Applicant respectfully requests withdrawal of the 35 U.S.C. §102(b) rejection of Claims 1-4, 6, 7, 10, 11, and 14-18. New Claims 19 and 20 depend from Claim 1, and thus are allowable over Brace for at least this reason. New independent Claim 21 is allowable for at least the reasons noted above. New Claims 22-24 depend directly or indirectly from Claim 21, and thus are allowable for at least this reason.

***Rejections Under 35 U.S.C. §103***

1. Claim 4 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Brace in view of U.S. Patent Application Publication No. 2003/0135210 applied for by Dixon, *et al.* ("Dixon").

Claim 4 depends from Claim 1. Dixon fails to cure the deficiencies of Brace noted above with regard to Claim 1 because Dixon is cited by the Examiner in an attempt to teach that "said assembly element is a threaded nut built into said rigid body," as recited in Claim 4. Since neither Brace nor Dixon teaches "said saddle clamp having a rigid body with a contact surface for contacting the vertebra and comprising a saddle surface configured to straddle the top of the pedicle between the transverse process and the superior facet when said saddle clamp is mounted on the vertebra, and a second surface configured to contact simultaneously said superior facet," as recited in Claim 1, even if one of ordinary skill in the art happens to combine the teachings of the two references, the combined references still do not teach these features of Claim 1. Accordingly, Claim 4 is allowable over Brace and Dixon, whether taken alone or in combination.



2. Claim 9 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Brace.

Claim 9 has been canceled without prejudice or disclaimer, thereby rendering the rejection thereto moot.

3. Claims 10-12 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Brace in view of Dixon.

Claims 10-11 depend directly or indirectly upon Claim 1. Dixon fails to cure the deficiencies of Brace noted above with regard to Claim 1 because Dixon is cited by the Examiner in an attempt to teach the additional features of dependent Claims 10-11. Since neither Brace nor Dixon teaches "said saddle clamp having a rigid body with a contact surface for contacting the vertebra and comprising a saddle surface configured to straddle the top of the pedicle between the transverse process and the superior facet when said saddle clamp is mounted on the vertebra, and a second surface configured to contact simultaneously said superior facet," as recited in Claim 1, even if one of ordinary skill in the art happens to combine the teachings of the two references, the combined references still do not teach these features of Claim 1. Accordingly, Claims 10-11 are allowable over Brace and Dixon, whether taken alone or in combination. Claim 12 has been canceled without prejudice or disclaimer, thereby rendering rejection thereto moot.

4. Claim 13 stands rejected under 35 U.S.C. §103(a) as being unpatentable over

Brace in view of Dixon, in further view of U.S. Patent No. 5,665,086 issued to Itoman, *et al.* ("Itoman").

Claim 13 has been canceled without prejudice or disclaimer, thereby rendering rejection thereto moot.

5. Claims 14-18 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Brace in view of Dixon, in further view of U.S. Patent No. 5,306,275 issued to Bryan ("Bryan").

Claims 14-18 depend indirectly upon Claim 1. Dixon and Bryan fail to cure the deficiencies of Brace noted above with regard to Claim 1 because Dixon and Bryan are cited by the Examiner in an attempt to teach the additional features of dependent Claims 14-18. Since none of Brace, Dixon, and Bryan teaches "said saddle clamp having a rigid body with a contact surface for contacting the vertebra and comprising a saddle surface configured to straddle the top of the pedicle between the transverse process and the superior facet when said saddle clamp is mounted on the vertebra, and a second surface configured to contact simultaneously said superior facet," as recited in Claim 1, even if one of ordinary skill in the art happens to combine the teachings of the three references, the combined references still do not teach these features of Claim 1. Accordingly, Claims 14-18 are allowable over Brace, Dixon, and Bryan, whether taken alone or in combination.

New Claims 19 and 20 are allowable because they depend from allowable Claim 1.

New independent Claim 21 explicitly describes the term "saddle surface" in accordance with the specification, page 10, lines 19-21, thereby making the claim literally differentiate those disclosed by Brace, and thus is allowable for at least this reason.

New Claims 22-24 depend directly or indirectly from Claim 21, and thus are allowable for at least this reason.

Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection of Claims 4 and 9-18. Since none of the other prior art of record, whether taken alone or in any combination, discloses or suggests all the features of the claimed subject matter, Applicant respectfully submits that independent Claims 1 and 21, and all the claims that depend therefrom, are allowable.

### CONCLUSION

Applicant believes that a full and complete response has been made to the pending Official Action and respectfully submits that all of the stated grounds for rejection have been overcome or rendered moot. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicant's undersigned representative at the number below to expedite prosecution.

If an extension of time is necessary to prevent abandonment of this application and is not filed herewith, then such extension of time is hereby petitioned for under 37 C.F.R. §1.136(a). Any fees required for further extensions of time and any fees for the net addition of Claims are hereby authorized to be charged to our Deposit Account No. 14-0112. Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,  
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